



Food and Drug Administration
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May 6, 2015

Vascular Flow Technologies Ltd.
Edwin Lindsay
VP of Quality and Regulatory
Prospect Business Centre
Gemini Crescent,
Dundee,
DD2 1TY
United Kingdom

Re: K150389

Trade/Device Name: Spiral Flow Peripheral Vascular Graft

Regulation Number: 21 CFR 870.3450

Regulation Name: Vascular Graft Prosthesis

Regulatory Class: Class II

Product Code: DSY

Dated: April 3, 2015

Received: April 10, 2015

Dear Mr. Lindsay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150389

Device Name

Spiral Flow™ Peripheral Vascular Graft

Indications for Use (Describe)

The Spiral Flow Peripheral Vascular Grafts are indicated for use as vascular prostheses.

The device is intended for use in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Vascular Flow Technologies Ltd.
Special 510(k): Device Modification

For the Spiral Flow™ Peripheral Vascular Graft

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Vascular Flow Technologies Limited

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Date Prepared:

12th February 2015

Vascular Flow Technologies Ltd.
Special 510(k): Device Modification
For the Spiral Flow™ Peripheral Vascular Graft

510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
870.3450	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	Class 2	DSY	Cardiovascular

Device Trade Name:

Spiral Flow™ Peripheral Vascular Graft

Device Common Name:

Spiral Flow™ Peripheral Vascular Graft

Intended Use:

The Spiral Flow Peripheral Vascular Grafts are indicated for use as vascular prostheses.

The device is intended for use in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Predicate Device:

The modified device is substantially equivalent to the previously cleared Spiral Flow Peripheral Vascular Grafts, 510(k) numbers K083169 and K142062.

Device Description:

Vascular Flow Technologies' (VFT) Spiral Flow™ Peripheral Vascular Graft is to be used in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee; it has a specially designed section to induce spiral laminar flow.

The unique design feature translates Spiral Laminar Flow (SLF™) technology to the graft lumen profile. SLF™ technology is designed to propagate spiral flow through the graft and into the distal circulation.

The starting material for the VFT Spiral Flow™ Peripheral Vascular Graft is a straight tubular vascular graft made from expanded polytetrafluoroethylene (ePTFE).

The graft includes a helical overlay of polytetrafluoroethylene (PTFE) beading over most of the grafts length. This is heat set onto the external surface of the ePTFE tube. The function of the beading is to provide reinforcement for the tube.

Vascular Flow Technologies Ltd.
Special 510(k): Device Modification
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510(k) Summary

The unique SLF™ spiral flow inducer is injection molded onto the outer surface of the straight graft. The inducer and indicator are made from ChronoFlex® C-80A; a Biodurable Medical Grade polyurethane

Comparison to Predicate Device

In comparison to the predicate device, the subject device has a new base ePTFE graft material. This modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Summary of non-clinical tests:

The following outlines the testing performed, as a result of the risk analysis, to demonstrate substantial equivalence to the predicate device:

- Biocompatibility Review
- Product Testing - Characterisation Study
- Product Testing – Flow Testing Study
- Sterilisation Validation

Conclusion:

The above test results confirmed the modified device met or exceeded the same specifications as that of the predicate device and is therefore substantially equivalent with respect to safety and efficacy to the predicate device